(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date 1 May 2003 (01.05.2003)

PCT

(10) International Publication Number WO 03/035118 A2

(51) International Patent Classification⁷: A61L 2/00

(21) International Application Number: PCT/US02/34307

(22) International Filing Date: 25 October 2002 (25.10.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/351,676 25 October 2001 (25.10.2001) US 60/401,715 7 August 2002 (07.08.2002) US

(71) Applicant: STERIS INC. [US/US]; 43425 Business Park Drive, Temecula, CA 92590 (US).

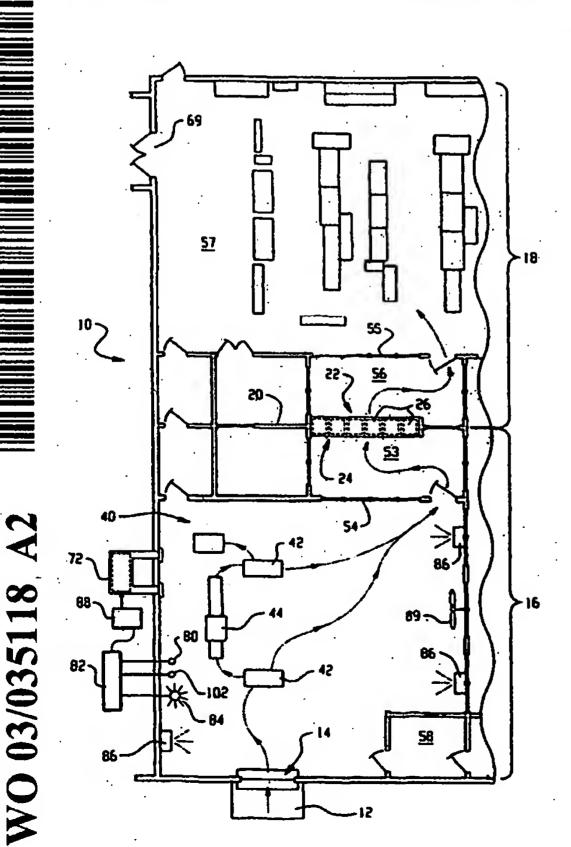
(72) Inventors: MIELNIK, Thaddeus, J.; 7546 Hunting Lake Drive, Concord, OH 44077 (US). KARLE, David, A.;

9201 Mohawk Road, Girard, PA 16417 (US). BIGGIE, Alex, D.; 5731 Silvertree Court, Madison, Oli 44057 (US). BIEBESHEIMER, William, John, Thomas; 4785 South Ridge Road, Perry, Oli 44081 (US). BURKE, Peter, A.; 7 Mayacoo Court, Skillman, NJ 08558 (US). MCDONNELL, Gerald, E.; 7 Millenium Court, Lower Brook Street, Basingstoke (GB). RHODES, Chad; 206 Briar Ridge Lane, Lake Villa, IL 60046 (US). KOPIS, Elaine, M.; 4545 Little Rock Road, St. Louis, MO 63128 (US).

- (74) Agents: KOCOVSKY, Thomas, E., Jr. et al.; Fay, Sharpe, Fagan, Minnich & McKee, LLP, 1100 Superior Avenue, 7th floor, Cleveland, OH 44114 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,

[Continued on next page]

(54) Title: DECONTAMINATION OF CRITICAL MAIL



(57) Abstract: A system for handling mail is in the form of a modular facility (10), which is capable of being isolated from the surrounding environment. The modular facility includes an enclosure or sorting area (40) for receiving and sorting incoming mail. A decontamination system (22) receives sorted mail and decontaminates the mail with a oxidizing gas, such as ethylene oxide. A clean room (32), isolated from the enclosure and spaced from the enclosure by the decontamination system, is used for receiving processed mail from the decontamination system and sorting the mail for distribution. A source (92) of a decontaminant gas, such as vapor hydrogen peroxide, is fluidly connected with the enclosure for supplying the decontaminant gas to the enclosure in the event that the sorting room is contaminated or suspected of being contaminated with a pathogenic biological or chemical agent.



LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK,

TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 03/035118 PCT/US02/34307

MEDZ 2 01310 PCT

DECONTAMINATION OF CRITICAL MAIL

Background of the Invention

invention relates present The to decontamination of sorting rooms, such as mailrooms, where there exists a possibility that biological or chemical contaminants may be introduced to the sorting room along with the items being sorted. It finds particular application in combination with a two-part decontamination system in which the mail items are subjected to a systematic high level decontamination process, while the sorting room and equipment therein are decontaminated periodically or intermittently, such as when a biological or chemical hazard is detected or suspected. It will be appreciated that the invention also finds utility in other applications and with other sterilization and decontamination techniques.

Mail sorting facilities, at corporations that are potential terrorist threats or which handle large volumes of mail, face the concern that a letter or package containing a hazardous material, such as a pathogenic bacteria or chemical agent, could enter the facility along with the regular mail. It has been found that mail sorting equipment is capable of releasing spores of *Bacillus anthracis*, the causative agent of anthrax, contained in sealed envelopes into the environment. The airborne spores contaminate other

10

WO 03/035118 PCT/US02/34307

-2-

mail and also the sorting equipment, posing hazards both to workers in the sorting room and to mail recipients.

The spores tend to travel beyond the original mail sorting room into other parts of the facility, such as through air ducts, doors, and windows, risking contamination to large areas of the facility. A single contaminated letter is capable of infecting an entire facility. This results in a considerable loss in time while remediation is effected, in addition to the risks posed to workers in the facility.

The present invention provides a new and improved system and method of treatment of mail handling facilities which overcome the above-referenced problems and others.

Summary of the Invention

In accordance with one aspect of the present invention, a method for handling mail is provided. The method includes receiving the mail in a preliminary sorting area, treating at least a portion of the mail with an oxidizing gas, and, in the event that the preliminary sorting area is contaminated or suspected of being contaminated with a pathogenic biological or chemical agent, supplying a decontaminating gas to the preliminary sorting area to decontaminate the sorting area and equipment and mail located within the preliminary sorting area.

In accordance with another aspect of the present invention, a method of decontaminating incoming mail is provided. The method includes receiving potentially contaminated mail in a first room that is sealed to the ambient environment and loading the mail into a pass through sterilizer from the first room. The mail is decontaminated in the sterilizer. From a second room isolated from the first room, the mail is removed from the sterilizer. After the mail is

10

20

25

10

15

20

25

30

removed from the sterilizer in the second room, the mail is sorted and processed.

In accordance with another aspect of the present invention, a system for handling mail is The system includes a facility which is provided. being isolated from the surrounding capable of environment. The facility includes an enclosure for receiving potentially contaminated incoming mail and a clean area, isolated from the enclosure, in which decontaminated mail is sorted for distribution. which decontamination system receives decontaminates the potentially contaminated mail is connected with the enclosure to receive the potentially contaminated mail therefrom and with the clean area to supply the decontaminated mail thereto.

In accordance with another aspect of the present invention, a system for handling potentially contaminated mail is provided. The system includes a dirty-side room in which the potentially contaminated mail is prepared for decontamination. A decontamination system is connected with the dirty-side room for bulk decontamination of the potentially contaminated mail. A source of decontaminant gas is connected with the dirty-side room for intermittently treating the dirty-side room for pathogenic biological or chemical agents.

One advantage of at least one embodiment of the present invention is that it reduces the hazards posed by potentially contaminated mail.

Another advantage of at least one embodiment of the present invention is that mail handling equipment and mail are separately and effectively decontaminated.

Still further advantages of the present invention will become apparent to those of ordinary skill in the art upon reading and understanding the

WO 03/035118 PCT/US02/34307

-4-

following detailed description of the preferred embodiments.

Brief Description of the Drawings

The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating a preferred embodiment and are not to be construed as limiting the invention.

FIGURE 1 is a schematic view of a mail handling facility in accordance with the present invention.

FIGURE 2 is a perspective view of a mobile 15 mail handling facility;

FIGURE 3 is a plot showing pressure changes throughout a vapor hydrogen peroxide decontamination cycle;

FIGURE 4 is a perspective rendering of a mail 20 handling facility in accordance with the present invention;

FIGURE 5 is a perspective rendering of a second embodiment of a mail handling facility in accordance with the present invention.

25

30

Detailed Description of the Preferred Embodiments

With reference to FIGURES 1 and 2, a mail handling facility 10 is shown. Items to be sorted, such as packages, letters, and other items of mail enter the facility from a loading dock 12 via an air lock 14 and undergo a preliminary sorting, are examined if appropriate, and distributed to different locations for different treatment. The facility provides for both routine decontamination of mail, even where no specific biological or chemical hazard has been identified, and for intermittent decontamination of the facility when a specific hazard risk has been identified.

facility includes a "dirty side" 16, where all incoming mail items are treated as being potentially contaminated with a biological or chemical pathogenic agent, such as anthrax, small pox, LSD, nerve gas or the like, and a "clean side" 18, where the items are processed without concern for contamination, having been subjected to a decontamination process. The clean side 18 is separated from the dirty side 16 by a pathogenic agent impermeable barrier 20, such as a wall. Between the dirty side 16 and the clean side 18, the items pass through a pass-through decontamination system 22, designed to destroy any potential pathogenic agents which may be associated with the items. decontamination system 22 may be a single sterilizer or more than one sterilizer. 15

Biological pathogenic agents, as used herein microorganisms, such as bacterial means spores, vegetative bacteria, viruses, molds, and fungi capable of killing or causing severe injury to mammals, particularly humans. Included among these are viruses, 20 such as equine encephalomyelitis and smallpox; bacteria, such as those which cause plague (Yersina pestis), anthrax (Bacillus anthracis), and tularemia (Francisella tularensis); funqi, and such coccidioidomycosis; as well as toxic products expressed 25 by such microorganisms; for example, the botulism toxin expressed by the Clostridium botulinium common bacterium.

Chemical pathogenic agents include poison gases and liquids, particularly those which are volatile, such as nerve gases, blistering agents (also known as vesicants), and other extremely harmful or toxic chemicals. As used herein, the term "chemical pathogenic agent" is intended to include only those agents which are effective in relatively small dosages to injure, disable or kill mammals and which can be degraded or otherwise rendered harmless by a process

which includes oxidation. Exemplary chemical pathogenic agents include choking agents, such as phosgene; blood agents, which act on the enzyme cytochrome oxidase, as cyanogen chloride and such hydrogen incapacitating agents, such as 3-quinuclidinyl benzilate ("BZ"), which blocks the action of acetylcholine; vesicants, such as di(2-chloroethyl) sulfide (mustard gas or"HD") and dichloro(2chlorovinyl)arsine (commonly known as Lewisite); nerve agents, such as ethyl-N, N dimethyl phosphoramino 10 cyanidate (commonly known Tabun or agent GA), as o-ethyl-S-(2-diisopropyl aminoethyl) methyl phosphonothiolate (commonly known as agent VX), isopropyl methyl phosphonofluoridate (commonly known as Sarin or Agent GB), methylphosphonofluoridic 15 acid 1,2,2trimethylpropyl ester (commonly known as Soman or Agent GD). Chemical pathogens also includes substances which temporarily or permanently disable people or mammals.

The term "chemical pathogenic agent" includes substantially pure chemical compounds, but the term 20 also contemplates mixtures of agents in any proportions, as well as those agents in impure states. "Chemical pathogenic agents," as used herein, also includes partially or completely degraded chemical pathogenic agents, e.g., gelled, polymerized, 25 otherwise partially or totally decomposed chemical warfare agents.

The decontamination system 22 is designed to handle a regular throughput of incoming mail, such as is received daily in a mail sorting facility for a large company or government body. The decontamination system may be designed to handle all mail entering the facility, or mail may be sorted into classes, and only certain classes of mail subjected to decontamination.

35 Alternatively, different decontamination systems are employed for different classes of mail. For example, remittance mail may be treated with a form of radiation

effective for destroying microorganisms, such as electron beam radiation (produced by an electron accelerator) or gamma radiation, while other mail is decontaminated with ethylene oxide. Ionizing radiation, particularly of short wavelength, such as gamma and ebeam radiation, destroys microorganisms by breaking chemical bonds in biologically important molecules such as DNA, and by creating free radicals and reactive molecules which chemically attack the organism.

In an alternative embodiment, ionizing radiation is used for decontamination of all types of mail, including remittance mail and mail classed as critical.

In yet another embodiment, a multi-component vapor, such as hydrogen peroxide, is used for decontamination of all or part of the mail.

Ethylene oxide is a particularly preferred oxidant for regular treatment of incoming mail. It has good materials compatibility, being safe for use with paper, CDs, electronic storage media, video disks, and 20 A preferred decontamination system 22 the like. includes a bank 24 of ethylene oxide sterilizers, each with a sterilization chamber 26. Interlocking doors 28, 30 are provided on the clean and dirty sides of each chamber 26, the dirty side door 28 remaining locked 25 when the clean side door 30 is opened, and vice versa. Specifically, each chamber 26 has its own entrance door 28, on the dirty side, through which potentially contaminated items are loaded into the sterilization chamber 26. Each chamber also has an exit door 30 on 30 the clean side 18, through which decontaminated items are removed from the chamber into a clean room 32, where further sorting and distribution takes place. As illustrated in FIGURE 2, the decontamination system 22 forms part of the wall 20, with the dirty side entrance 35 doors 28 on one side of the wall and the clean side exit doors 30 on the other side of the wall. The clean

10

15

25

30

side 18 is thus isolated from the dirty side 14 of the facility.

The ethylene oxide sterilizers 26 may be analogous to those found in hospitals for treating contaminated medical instruments, as described, for example, in U.S. Patent No. 4,241,010. One such Eagle 3017 sterilizer suitable sterilizer is an obtainable from STERIS Corp. having interlocking double doors and a chamber size of about 5 cu. ft. A bank 24 of 8-12 such sterilizers is capable of handling about 50,000 pieces of mail a day. It is preferable to use a number of small sterilizers (i.e., less than about 10 cu.ft. chamber size), rather than a larger sterilizer, since the hazards posed by the quantities of ethylene oxide in much larger chambers generally demand the use of blended gas at higher pressures.

Prior to sterilization, the chamber 26 is evacuated to a pressure of about 60-90 torr, or less. Several vacuum pulses are preferably employed to improve removal of air trapped in the items. Ethylene 20 oxide from a cartridge or bulk supply (not shown) is then fed to the chamber 26 to bring the chamber to an above-atmospheric pressure, such as about 8 psig. sterilization phase, During the the chamber is preferably warmed, for example to about 55°C. The time taken for decontamination depends on the several factors, such as the volume and density of mail items, and the level of assurance desired. For high levels of assurance, e.g., about 10^{-8} (no more than 1 in 10^{8} pathogenic species remaining after decontamination), a decontamination time of about 1-4 hours is preferred, most preferably, about 2 hrs.

The chamber 26 is then evacuated and/or aerated to remove residual ethylene oxide from the chamber and items being decontaminated. Ethylene oxide 35 diffuses slowly from "hard" polymers, such as acrylic and amide polymers, polyvinylchloride, and from kraft

WO 03/035118 PCT/US02/34307

-9-

paper and glassine paper. Thus, a combination of vacuum and aeration is preferably used to speed removal of the residual ethylene oxide. For some items, such as those made from leather, diffusion is so slow that it is preferable to avoid ethylene oxide treatment of these items. One or more aeration cycles may be used in which air is admitted to the chamber and then removed by vacuum, to ensure that ethylene oxide which has absorbed into the items is removed. Typically, the aeration/evacuation portion of the cycle is longer than the decontamination portion, to ensure that ethylene oxide concentration in the mail is below an acceptably safe level. For example, the aeration portion of the cycle may be about 5-20 hrs, preferably about 10-15 The total time between loading the items hours. through the dirty side doors and unloading the decontaminated items via the clean side doors 30 is thus about 15 hours.

optionally, or additionally, a separate aerator 38 (FIGURE 4) is used for final aeration of the processed items, leaving the sterilizer chamber 26 free to handle another batch of unprocessed mail. Other sterilization systems, such as electron (e⁻) beam sterilizers, can also separate the clean and dirty sides.

The dirty side 20 includes an enclosure, such as a preliminary sorting area or mail handling room 40, which houses the preliminary sorting equipment, such as sorting tables 42 and an x-ray scanner 44. The x-ray scanner 44 is used to examine suspicious packages, or all packages of above a certain size, to determine the contents. Items which are determined to pose a potential threat during or after sorting, or which contain items which are not readily handled by the decontamination system, such as food items, leather, and foil packages, are separated out and disposed of or subjected to special treatment in a separate isolation

5

10

15

30

area. Other mail is sorted at the sorting tables into classes which are to be pathogenically decontaminated or which are deemed safe to be distributed without pathogenic decontamination. Mail which is to be pathogenically decontaminated is loaded into receptacles, such as wire baskets or totes 46, of a suitable size to be loaded into the decontamination system 26.

Ethylene oxide monitors 50,52, such as Eagle

Eto monitors available from STERIS Corp., are used in
both the clean side 18 and dirty side 16 regions to
ensure that workers are not subjected to ethylene oxide
levels above a safe level in the event of a leakage.
An area 53 adjacent the bank of sterilizers 26 is
optionally separated from the rest of the sorting area
by a plexiglass or glass wall 54 to minimize potential
risks of ethylene oxide exposure. A second plexiglass
or glass wall 55 isolates a sterilizer unloading region
56 of the clean room from an existing or conventional
mail handling or sorting area 57 of the clean room.

Workers enter and leave the sorting room 40 through a changing room 58, where they suit up in appropriate protective garments to protect them against potential hazards. For example, microbe impermeable suits, boots, gloves, hats and face masks are worn. the event of a determined or suspected contamination of the sorting room 40 by a pathogenic agent, workers exit the sorting room into the changing room 58 where they remove potentially contaminated clothing and wash in decontaminating cleansers. Suitable cleansers include those sold under the trade names CAL-STATTM, ALCARETM, and ALCARE PLUS™, available from STERIS Corp., which can be used with or without a water wash. Workers may be quarantined in an area of the changing room until they can be given appropriate medical attention if the suspected pathogenic contamination is determined to be particularly hazardous or contagious.

25

30

The dirty side 16 (preliminary sorting room 40 and sterilizer loading area 53) is isolated from other areas of the site or building in which it is housed. The sorting room, decontamination system 22, 5 and optionally also the clean room 32 conveniently form a modular unit 60 which is transported, e.g., by a truck, to a site where mail handling is to take place. The modular unit 60 optionally has its own wheels 62 (FIGURE 2), allowing it to be maneuvered around a site or between sites. The modular unit may be parked 10 outside a facility to reduce the risk of crosscontamination still further. Interior walls 64, a ceiling 66, and a floor 68 of the unit 60 define the sorting room 40 and optionally also the clean room 32, 15 or a portion thereof. The clean side optionally has doors 69, which connect to the loading dock or mail receiving door of an existing sorting facility.

The modular unit 60 is designed to maintain airtight an space within the 70 dirty side (particularly 20 sorting room 40 and preferably also sterilizer loading area 53), where pathogenic contamination can be treated without risk of contamination to the clean room 32, or other areas of the site. Accordingly, the room 40 has its own independent air handling system 72, such as a heating, ventilating, and air conditioning (HVAC) system, for supplying air to the room 40 and for treating outgoing air from the room. The air is recycled at a high frequency, such as ten changes per hour, to minimize the chance that workers will be exposed to airborne 30 contaminants. The room 40 preferably operates under a slight sub-atmospheric pressure, such that air tends to be sucked into the room 40, rather than leaving through doors and small openings. The HVAC system 72 has several inlets 74 and outlets 76, spaced throughout the 35 room 40, through which purified incoming air enters the sorting room 40 and used air exits the sorting room.

For facilities where large volumes of mail are to be handled, it is preferable to add additional modules 60, each one isolated from the others, so that if one of the modules' preliminary sorting rooms 40 is contaminated, the remaining modules 60 are able to continue with mail handling operations.

Within the sorting room 40, sensors 80 detect the presence of pathogenic agents. Preferably several sensors are provided which detect for different agents. Additionally, several sets of the sensors may be 10 positioned at different locations within the room. U.S. Patent No. 6,391,624, for example, describes a sensor capable of detecting anthrax and other clostridium and bacillus bacteria. The sensors 80 are hooked up to a central control system 82, which signals an alarm 84, such as a flashing light and/or audible alarm, in the event that one or more sensors 80 detects a pathogenic agent at a level above a predetermined threshold level. It is to be appreciated that many pathogenic organisms and chemicals are not readily detected by currently 20 available sensors. Accordingly, the control system 82 has a manual component which relies on worker input in the event that a suspected release of a pathogenic agent has occurred. For example, workers may detect a smell, observe the release of a fine powder from a .25 package, feel nauseous, or suffer other symptoms which they have been trained to associate with the potential release of a pathogenic agent. The alarm 84 may be actuated by a worker who determines that there is a risk of exposure to a suspected pathogenic agent. 30

The activation of the alarm 84 is a signal to the workers in the sorting room 40 that they should evacuate the sorting room and enter the changing area 58. Workers dressed in full biological hazard attire may enter the sorting room and apply a decontaminant spray to a suspicious package or letter. Alternatively, automated spray systems 86 are operated from outside

WO 03/035118 PCT/US02/34307

-13-

the sorting room to direct a spray or fog over suspected contaminated items. For example, the spray systems 86 may release a liquid spray, fog or mist of an antimicrobial, antiviral, and sporicidal chemical known to be effective against a broad spectrum of known pathogenic agents. One suitable chemical for use as a spray is a liquid mixture of hydrogen peroxide and peracetic acid, which is effective at destroying biological pathogens on surfaces it contacts. Such a composition exhibiting broad spectrum activity is available from STERIS Corp. under the trade name SPOR-This liquid composition is capable of KLENZ. decontaminating contaminated mail in about fifteen to twenty minutes. It is safe for use with a variety of surfaces, including stainless steel, plastics, glass, floors, and walls.

Once the control system 82 detects that all workers have been evacuated from the sorting room, e.g., by using motion sensors (not shown), the room is sealed by closing and locking the doors 14. Air vents, if any, which are open to the atmosphere or to clean areas of the facility are closed. A decontamination of the entire sorting room 40 is then carried out with a system decontamination 88 that to room ensure pathogenic agents are destroyed or otherwise rendered harmless. The decontamination is preferably carried out with a gaseous oxidizing agent, such as hydrogen peroxide in vapor form. Hydrogen peroxide vapor has been shown to be effective against a variety of known biological and chemical pathogenic agents, such as hard 30 destroy spores of Bacillus stearothermophilus, Bacillus anthracis, smallpox virus, and the like. is also effective at or close to room temperature (e.g., 15-30°C), making it suitable for decontamination of large enclosures, such as rooms. Hydrogen peroxide 35 vapor has a good material compatibility, rendering it safe for use with a variety of equipment and materials,

10

including electronic equipment, such as computers. It also degrades to water and oxygen over time.

To destroy harmful biological pathogens in air and on surfaces throughout the room 40, it has been found that a concentration of hydrogen peroxide of 1-2mg/L, or more at 25°C is effective to about decontaminate a room in about 6-8 hours, or less. Longer times may be used at lower concentrations, or shorter times at higher concentrations. The vapor is preferably in the "dry" state, i.e., below the 10 saturation point of the vapor, which varies with temperature. This avoids droplets of the condensing on items in the room, which both reduces the effectiveness of the vapor and increases the time needed to remove the residual hydrogen peroxide after 15 the vapor decontamination cycle is complete. Keeping the vapor in the dry state also reduces the risk of damage to electronic components and other susceptible to water damage.

20 in FIGURE 3, a typical shown As hydrogen peroxide decontamination cycle consists of four phases: (1) dehumidification, where the room's HVAC system 72, or a separate dehumidifier, is used to reduce the level of moisture in the room, conditioning, where the concentration of 25 hydrogen peroxide is gradually increased by supplying hydrogen peroxide vapor to the room, (3) decontamination, where pathogenic biological agents are inactivated (often referred to as sterilization) and pathogenic chemical agents are oxidized to a form in which their pathogenic 30 character is reduced or eliminated, and (4) aeration, where the HVAC system 72 is used to circulate fresh air into the room to reduce the hydrogen peroxide to safe levels (typically about 1 ppm, or less).

Preferably, the hydrogen peroxide is supplied to the sorting room 40 via the room's HVAC system 72.

One suitable hydrogen peroxide decontamination system

PCT/US02/34307 WO 03/035118

-15-

88 suited to use with a HVAC system is a VHP® M1000 modular system, available from STERIS Corp. Alternatively, a separate unit 88 is used to supply the vapor to the room, through dedicated ductwork, such as 5 a VHP® 1000, available from STERIS Corp. Such systems 88 are capable of sterilizing enclosures of up to 200,000 cu. ft. For larger enclosures, multiple hydrogen peroxide vapor generation systems 88 are used. Within the sorting room 40, fans 89 are activated to ensure distribution of the hydrogen peroxide, or other decontaminant vapor throughout the room.

The hydrogen peroxide vapor is readily formed from a solution of hydrogen peroxide in water, such as a 35% hydrogen peroxide solution, which is supplied 15 from a reservoir 90, such as a tank, to a vapor generator 92. The generator 92 converts the liquid to a vapor, for example, by bringing droplets or a mist of the solution into contact with a heated plate or tube (not shown). Other gaseous oxidizing agents may be used, such as peracids, e.g., peracetic acid vapor, 20 ozone, or chlorine gas, alone, or in combination with more gaseous oxidants including hydrogen one or peroxide vapor.

A carrier gas, such as air, is supplied to the vaporizer 92 via a carrier gas line 94 to mix with the liquid and/or vapor and carry the vapor out of the vaporizer 92. The carrier gas may be filtered by a filter 96, dehumidified by a dehumidifier 98, and optionally heated by a heater 100 before entering the vaporizer 92. The vapor and carrier gas mixture is fed 30 into the ducts 78 of the HVAC system and carried along with the filtered air to the room inlets 74.

It will be appreciated that where vapor hydrogen peroxide is used in a decontamination system in place of ethylene oxide, a vapor hydrogen 22, 35 peroxide generation system similar to the system 88

described above is optionally used to supply hydrogen peroxide vapor to the sterilization chamber 26.

One, or preferably several hydrogen peroxide sensors 102 in the sorting room 40 detect the level of hydrogen peroxide and/or water vapor in the sorting room to ensure that the hydrogen peroxide level in the room is maintained at a preselected level. The sensor 102 is connected with the control system 82, which adjusts the rate of introduction of hydrogen peroxide to the vaporizer, air flow rates, or the like, in 10 detected hydrogen response to peroxide/water concentrations, to maintain the selected hydrogen peroxide concentration in the room 40. Suitable hydrogen peroxide sensors 102 are those which use infrared absorption by the vapor circulating in the 1.5 room 40. The sensor preferably operates in a region of the infrared spectrum where water and/or hydrogen peroxide absorbs strongly, to provide a measure of the hydrogen peroxide concentration.

After the room sterilization phase is complete, the sensors 102 can be used to determine when the levels of hydrogen peroxide in the room 40 have dropped to a level at which it is safe for the workers to reenter. Additional hydrogen peroxide sensors 104 may be placed in the HVAC exhaust system ducts to check that hydrogen peroxide is not being released to the atmosphere at unsafe levels.

With reference now to FIGURE 5, a mail handling facility 10, similar to that shown in FIGURES 1 and 2 is shown. The facility 10 is modular and operates as a self-contained unit, as for the facility of FIGURES 1 and 2. Items to be sorted, such as packages, letters, and other items of mail enter the facility from a loading dock via a door or airlock 14.

35 Airlock 14 may take the form of an ante-room, providing space for handling incoming mail, with inner and outer doors 106, 108.

In this embodiment, the incoming mail packaged, for example, at the Post Office or other sorting facility, in sealed containers, which are substantially impermeable to pathogens, such as airtight plastic totes 110. Prior to bringing the totes in to the facility 10, e.g., in the air lock, workers, preferably in hazardous material handling suits, spray the exterior surfaces of the totes with a liquid spray, fog or mist of an antimicrobial, antiviral, and sporicidal chemical known to be effective against a 10 broad spectrum of known pathogenic agents. suitable chemical for use as a spray is SPOR-KLENZ. The totes are left outside the facility for a sufficient time to ensure that any microbial contaminants on the totes are destroyed. Such contaminants may have been 15 picked up by the totes during handling at a central mail handling center or during transportation, for example, from having traveled in contaminated delivery trucks. For larger facilities, an automated spraying device, which treats the tote exteriors with the SPOR-20 KLENZ or other decontaminant spray, may be located in the airlock region.

Alternatively, or additionally, the interior of the delivery tuck, and/or its contents may be pretreated with a sporicidal spray, hydrogen peroxide vapor or the like, to rid the mail truck of contaminants. This is particularly helpful when the same truck is used to transport the decontaminated mail to another site. Within the facility 10, the incoming mail is removed from the totes 110 before undergoing processing.

As with the embodiments of FIGURES 1 and 2, the mail undergoes a preliminary sorting in a "dirty side" 16, where all incoming mail items are treated as being potentially contaminated with a biological or chemical pathogenic agent before passing to a "clean side" 18, where the items are processed without concern

for contamination, having been subjected to decontamination process. A pathogenic agent impermeable barrier 20, such as a wall or walls separates the clean and dirty side. A pass-through decontamination system 5 22 microbially decontaminates the mail. The decontamination system 22 preferably includes a bank of ethylene oxide sterilizers ormicrobial other decontamination system (e.g., e-beam, gamma radiation,hydrogen peroxide vapor, or the like, as previously discussed) to destroy any potential pathogenic agents 10 which may be associated with the items. After sorting, the decontaminated mail is repacked into totes 110, which have preferably been decontaminated, both inside Particularly where the totes of processed mail are to be transported by truck or other vehicle, 15 the totes are preferably air-tight to ensure that the processed mail does not become recontaminated by contact with contaminants in the truck. On reaching its finally destination, each tote may be re-sprayed with a sporicidal agent to ensure that the mail does not 20 become recontaminated during removal from the tote.

Alternatively, the totes 110 are packed in a microbe impermeable barrier, such as plastic or TyvecTM, which is removed from the totes at their final destination.

The pathogen treatment systems employed in the mail handling facility 10 can be extended to other areas of a mail delivery flowpath. Typically, mail enters the flowpath at a mailbox, from which pieces of mail are retrieved at regular intervals by postal workers. The mail is transported in sacks, cartons, or other handling devices to a local sorting hub. From the local sorting hub, the mail is transported to one or more distribution sorting hubs and is delivered to the recipients, such as the mail handling facility described above. At each step in the flowpath, there is a potential for contamination of workers or other

mail due to the handling procedures. Hazard Analysis and Critical Control Point (HACCP) principles are used to assess the risks at each step and appropriate hazard prevention methods applied. These methods need not be applied at all times. However, preparations are preferably made in advance such that the hazard prevention techniques are implemented when the assessed risk suggests that they are necessary.

For example, postal workers are provided with a antimicrobial spray or dusting compound, such as SPOR-KLENZTM, which is applied to the contents of a mailbox before the postal worker retrieves the mail therefrom. The postal worker waits for a few minutes before opening the mailbox to allow the spray to destroy pathogenic agents on the surfaces of the mail. The postal worker is then assured that the mail can be handled without posing a health risk.

Local sorting hubs and distribution sorting hubs are optionally fitted with mail decontamination systems 22 as described above, e.g., ethylene oxide, 20 gamma radiation, or e-beam sterilizers. Alternatively, all mail is sent to an offsite facility where it is passed through a mail decontamination system before returning to the hub for sorting. Room decontamination systems, such as the sorting room vapor hydrogen 25 peroxide decontamination system described above, are optionally used at each of the hubs for decontamination of sorting rooms when a potential release of a pathogenic agent is detected. Other areas where contamination is possible are also fitted with area 30 decontamination systems, such as offices, changing rooms, ventilation ducts, and the like. hydrogen peroxide vaporizer, for example, is capable of decontaminating a room or area of about 10,000 sq ft., or larger. For larger areas, multiple vaporizers are 35 preferably employed. Hand and body washes, such as Alcare™, Alcare Plus™, and Cal-Stat™ hand sanitizers,

available from STERIS Corp., are provided for workers either for use as a preventative treatment or for use after handling potentially contaminated mail. Transportation vehicles, such as trucks, planes, and rail cars, are periodically decontaminated to remove pathogens, or decontaminated when a risk of decontamination is expected.

Mail handling devices, including cartons, totes, sacks, sorting equipment, x-ray equipment, and the like are also subjected to periodic or intermittent decontamination. For example, totes, cartons, or sacks are periodically or intermittently passed through a decontamination system, such as decontamination system 22, and/or sprayed with a sporicidal agent.

15

Having thus described the preferred embodiment, the invention is now claimed to be:

1. A method for handling mail characterized by:

receiving the mail in a preliminary sorting area (40);

treating at least a portion of the mail with an oxidizing gas; and

in the event that the preliminary sorting area is contaminated or suspected of being contaminated with a pathogenic biological or chemical agent, supplying a decontaminating gas to the preliminary sorting area to decontaminate the sorting area and equipment (42, 44) and mail located within the preliminary sorting area.

2. The method of claim 1, further characterized by:

the oxidizing gas including ethylene oxide.

3. The method of claim 1 or 2, further characterized by:

the decontaminating gas including hydrogen peroxide vapor.

4. The method of any one of preceding claims 1-3, further characterized by:

sensing a pathogenic biological or chemical agent in the sorting area with a sensor (80);

the sensor signaling a control system (82) of the presence of the agent; and

the control system initiating the step of supplying the decontaminating gas in response to sensing a pathogenic agent above a predetermined acceptable level.

10

5

5

5

10

5. The method of any one of preceding claims 1-4, further characterized by:

supplying the decontaminant gas through a dedicated air handling system (72) for the sorting area.

6. The method of any one of preceding claims 1-5, further characterized by:

the sorting area forming part of a modular unit (60), the method further including:

transporting the modular unit to a site where the mail sorting and treating is to be carried out.

7. The method of any one of preceding claims 1-6, further characterized by:

sorting the treated mail, the step of sorting being carried out in a clean region (18) of the module which is isolated from the preliminary sorting area.

8. The method of any one of preceding claims 1-7, further characterized by:

the step of treating including:

loading mail in a basket (46) into the chamber (26) of a sterilizer (22);

evacuating the sterilizer; and introducing gaseous sterilant to the chamber, the mail being kept in the sterilizer for a sufficient time to decontaminate the mail.

9. The method of claim 8, further characterized by:

after the introducing step, aerating the chamber to remove residual sterilant.

5

5

5

10. The method of any one of preceding claims 1-9, further characterized by:

the step of sorting including separating the mail into mail which will be subjected to the treatment step and mail which is unsuited to be treated in the treatment step.

11. The method of any one of preceding claims 1-10, further characterized by:

prior to the step of sorting:

transporting the mail to the sorting area in an airtight container (110); and

removing the mail from the airtight container.

12. The method of claim 11, further characterized by:

prior to the step of removing, decontaminating an exterior surface of the container with a pathogenic agent.

13. The method of any one of preceding claims 1-12, further characterized by:

after the step of treating, transporting the treated mail in a container (110) which is substantially impermeable to pathogens.

14. A method of decontaminating incoming mail characterized by:

receiving potentially contaminated mail in a first room (40) that is sealed to the ambient environment;

loading the mail into a pass through sterilizer (22) from the first room;

decontaminating the mail in the sterilizer;

- from a second room (30) isolated from the

 first room, removing the mail from the sterilizer; and

 after the mail is removed from the

 sterilizer in the second room, sorting and processing
 the mail.
 - 15. The method of claim 14, further characterized by:

with all workers removed from the first room, treating the first room with a decontaminating vapor.

16. The method of claim 15, further characterized by:

monitoring the first room for contamination; and

- in response to sensing contamination, setting off an alarm (84) to cause workers to evacuate the first room and performing the treating step.
 - 17. The method of any one of preceding claims 14-16, further characterized by:

examining the mail in the first room with \mathbf{x} -rays.

18. The method of any one of preceding claims 14-17, further characterized by:

receiving the mail in sealed containers (110) in an ante-room (14) at an entrance to the first room; and

treating the exterior surfaces of the containers with a chemical decontaminant prior to loading the mail into the sterilizer.

19. The method of any one of preceding claims 14-18, further characterized by:

after the mail is removed from the sterilizer in the second room, packaging the mail in sealed containers for transport to another facility.

- 20. A system for handling mail characterized by:
- a facility (10) which is capable of being isolated from the surrounding environment, the facility including an enclosure (40) for receiving potentially contaminated incoming mail;
- a clean area (18), isolated from the enclosure in which decontaminated mail is sorted for distribution; and
- a decontamination system (22) which receives and decontaminates the potentially contaminated mail, the decontamination system being connected with the enclosure to receive the potentially contaminated mail therefrom and with the clean area to supply the decontaminated mail thereto.
 - 21. The system of claim 20, further characterized by:
 - a source (92) of a decontaminant gas, fluidly connected with the enclosure for supplying the decontaminant gas to the enclosure in the event that the enclosure is contaminated or suspected of being contaminated with a pathogenic biological or chemical agent.
 - 22. The system of claim 20 or 21, further characterized by:

the system being modular.

23. The system of any one of preceding claims 20-22, further characterized by:

the decontamination system including an ethylene oxide sterilizer.

5

24. The system of any one of preceding claims 20-23, further characterized by:

the decontaminant gas including vapor hydrogen peroxide.

25. The system of any one of preceding claims 20-24, further characterized by:

the decontamination system including a passthrough chamber (26), the pass-through chamber including a first door (28) which communicates with the enclosure and a second door (30) which communicates with the clean area.

- 26. The system of claim 25, further characterized by:
- a control system (82) which locks the first door against opening when the second door is open.
- 27. The system of claim 21, further characterized by:
- a dedicated HVAC system (72), the source of the decontaminant gas being fluidly connected with the 5 HVAC system.
 - 28. The system of any one of preceding claims 20-27, further characterized by:
- an ante-room (14) connected with the enclosure through which the potentially contaminated mail is received.
 - 29. The system of any one of preceding claims 20-28, further characterized by:

sealed containers (110) which carry the potentially contaminated mail, the sealed containers being adapted for treatment with sporicidal agents.

5

5

5

30. The system of any one of preceding claims 20-29, further characterized by:

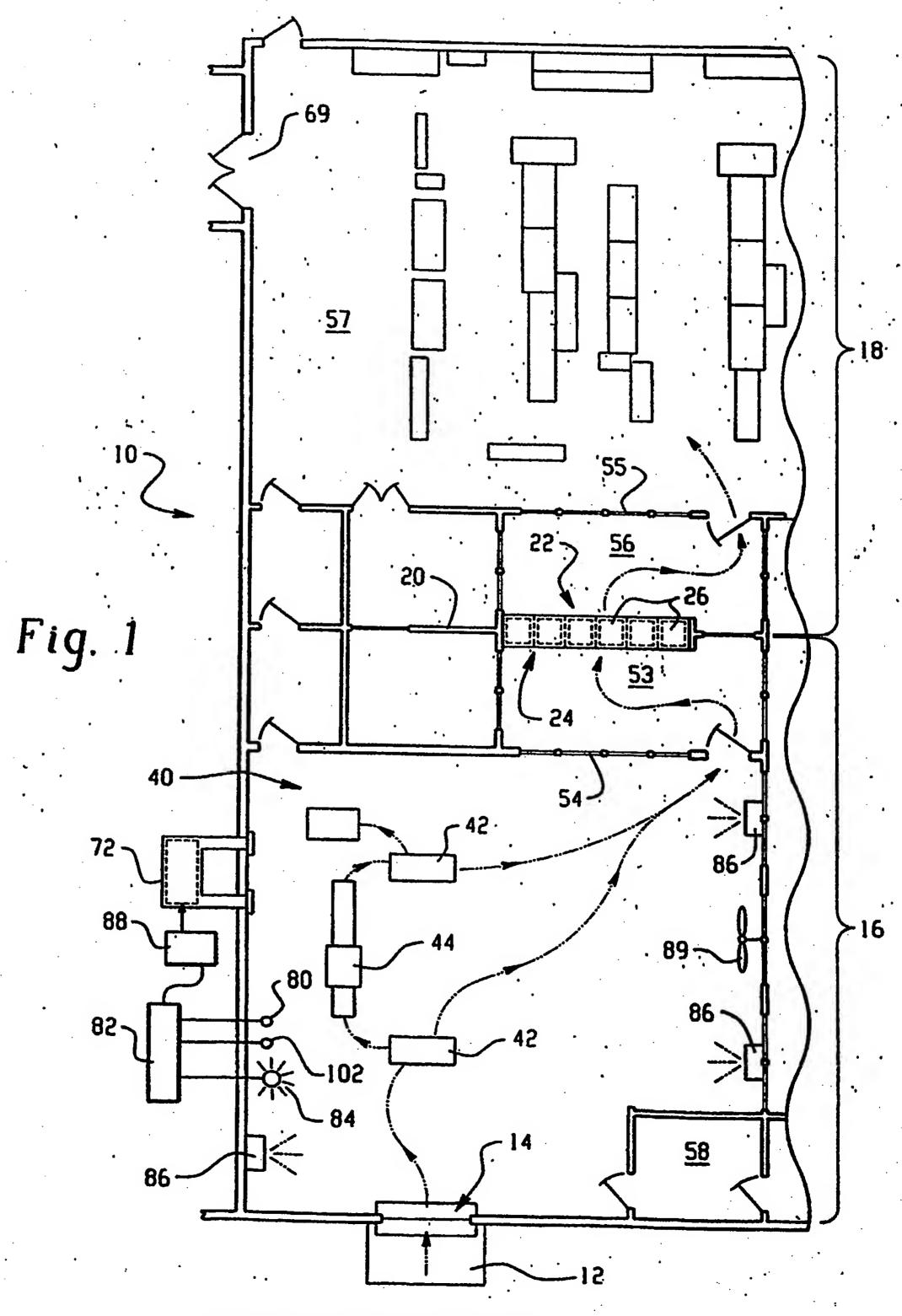
an x-ray unit (44) in the enclosure to examine the potentially contaminated mail for items that are inappropriate for treatment with the decontamination system.

- 31. A system for handling potentially contaminated mail characterized by:
- a dirty-side room (40) in which the potentially contaminated mail is prepared for decontamination;
- a decontamination system (22) connected with the dirty-side room for bulk decontamination of the potentially contaminated mail; and
- a source (92) of decontaminant gas connected 10 with the dirty-side room for intermittently treating the dirty-side room for pathogenic biological or chemical agents.
 - 32. The system of claim 31, further characterized by:
 - a clean-side room (32) connected with the decontamination system and isolated from the dirty-side room.
 - 33. The system of claim 31 or 32, further characterized by:

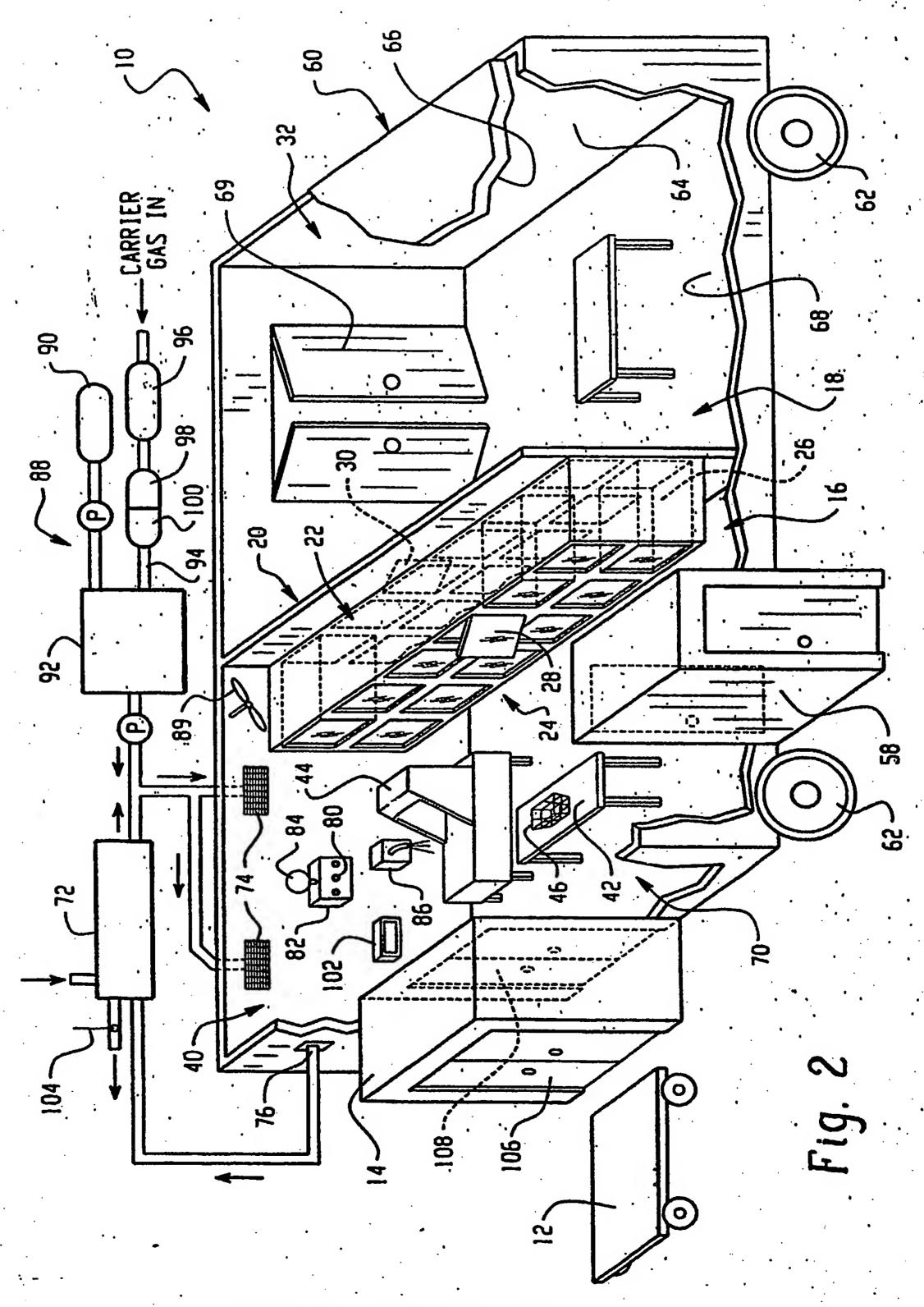
pathogenic agent sensors (80) mounted in the dirty-side room.

34. The system of any one of preceding claims 31-33, further characterized by:

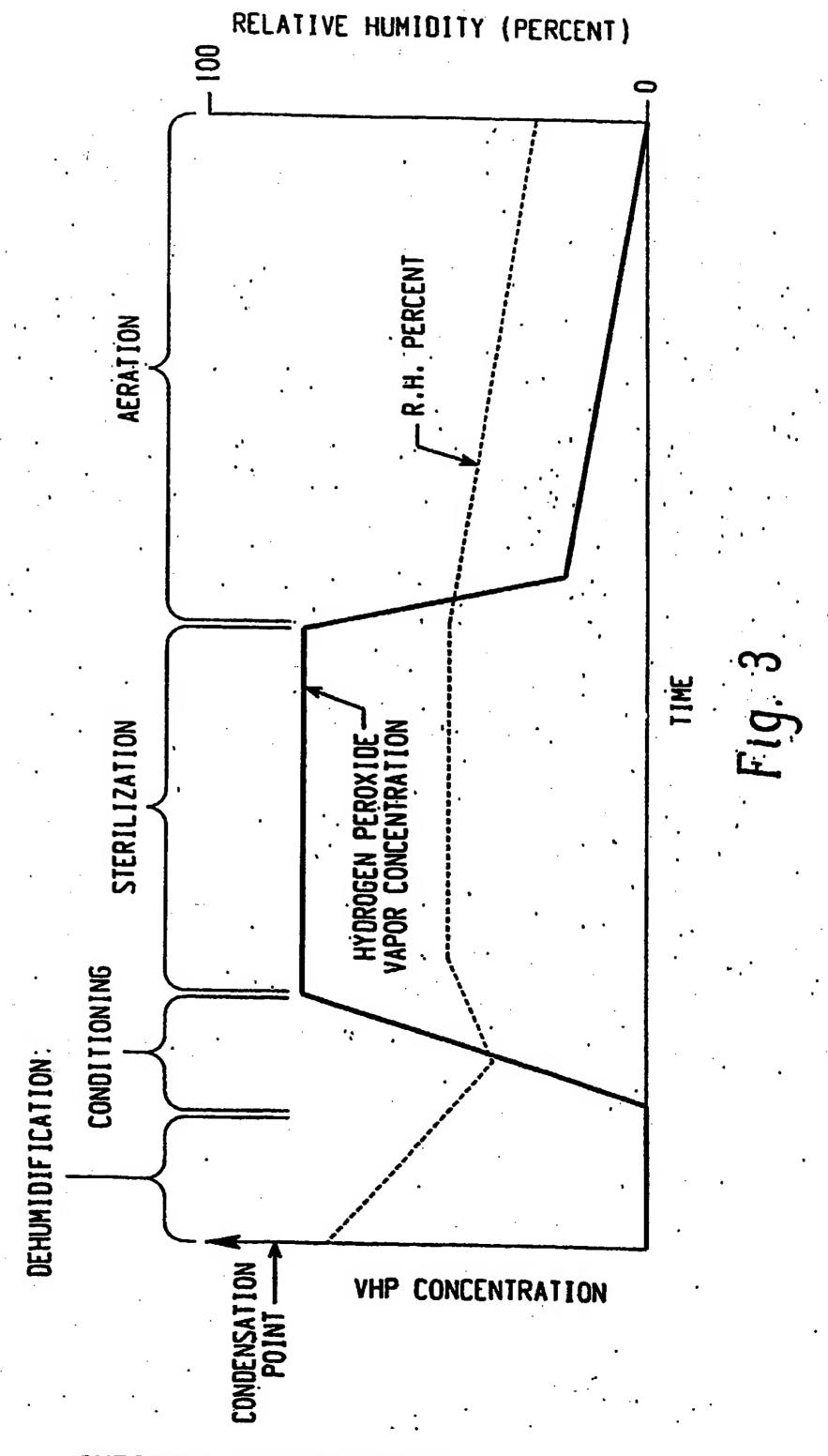
the decontaminant gas being hydrogen peroxide vapor.



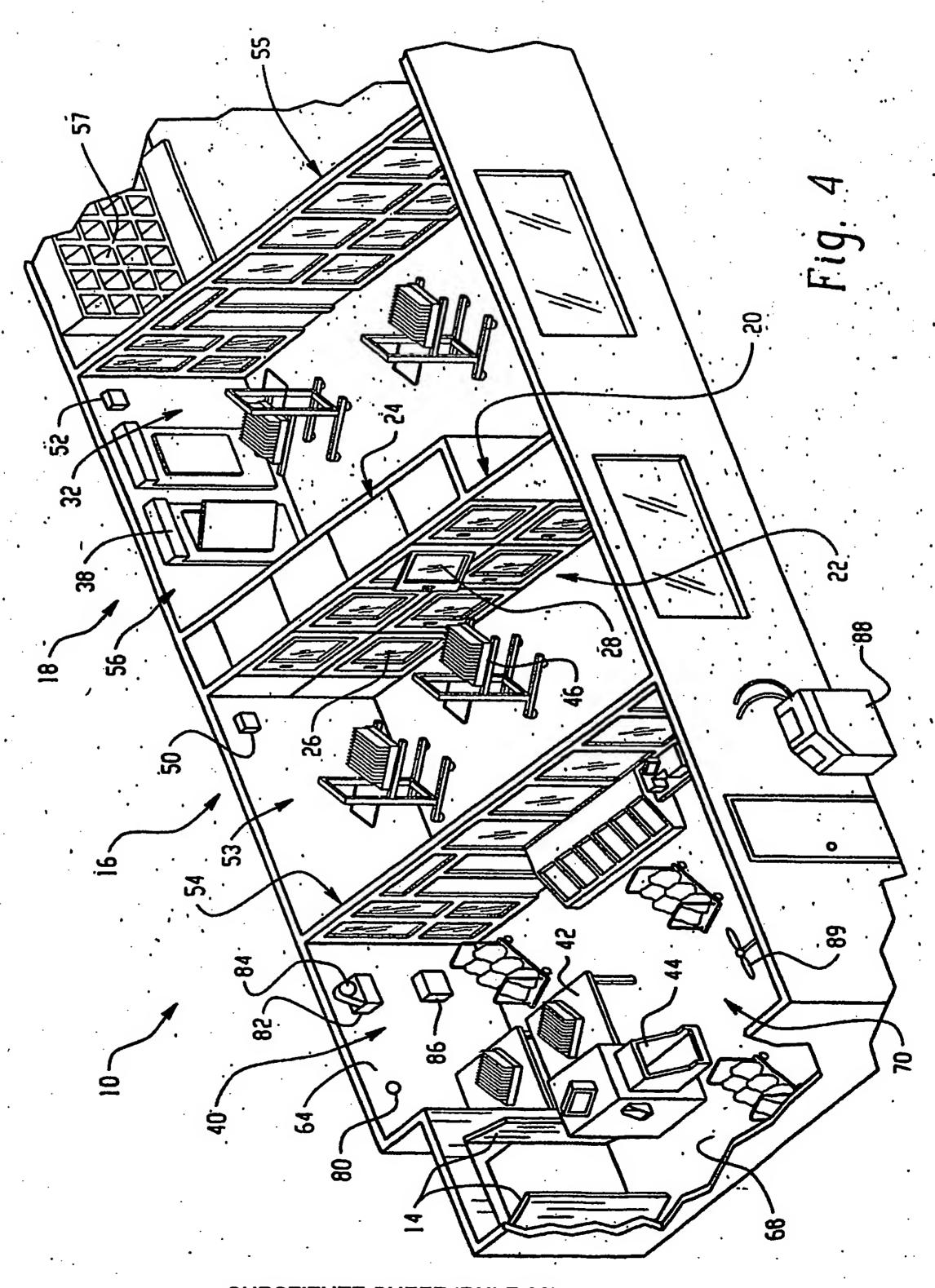
SUBSTITUTE SHEET (RULE 26)



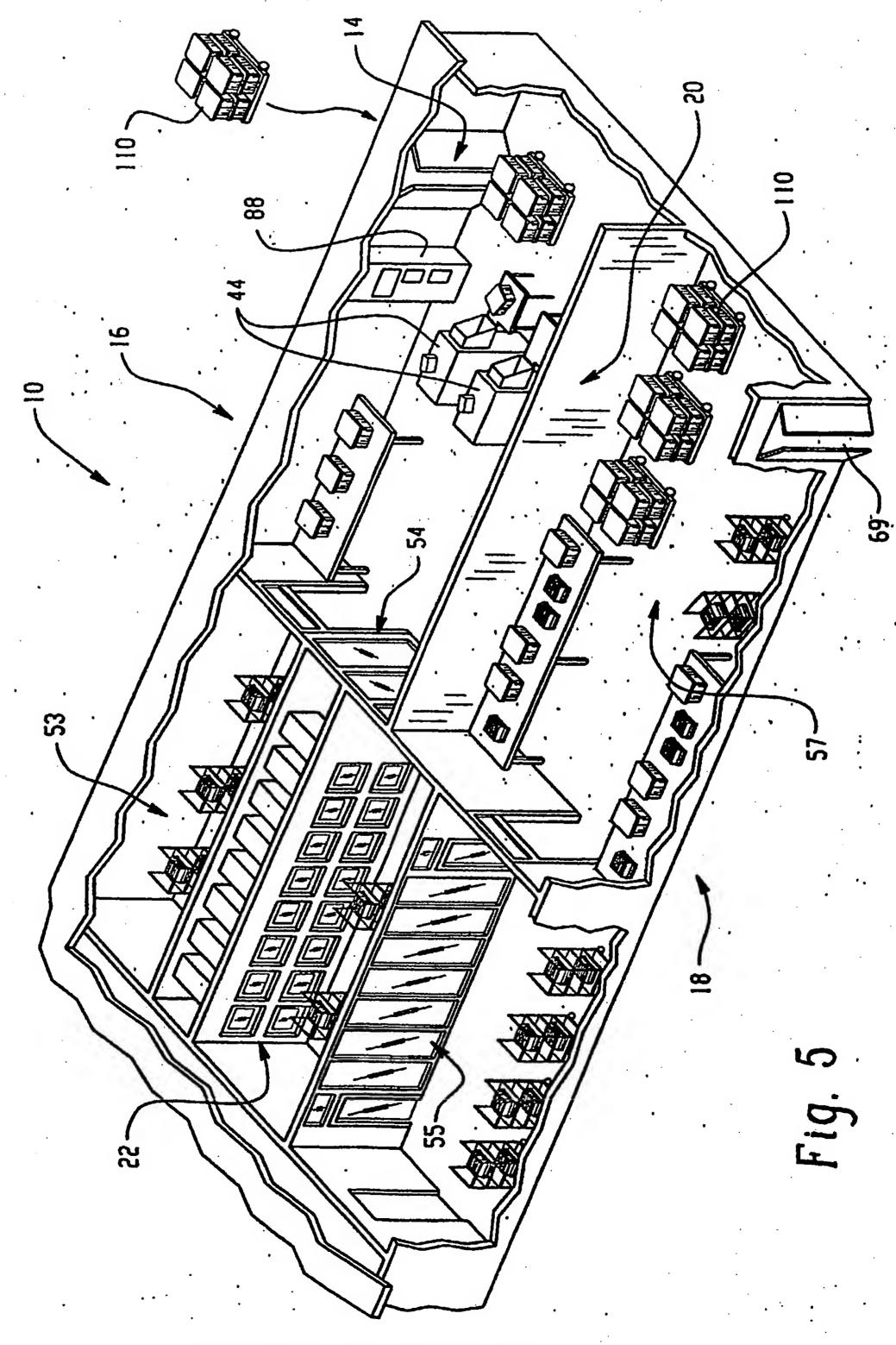
SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date 1 May 2003 (01.05.2003)

PCT

(10) International Publication Number WO 03/035118 A3

(51) International Patent Classification⁷: A6

A61L 2/20

(21) International Application Number: PCT/US02/34307

(22) International Filing Date: 25 October 2002 (25.10.2002)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

60/351,676 60/401,715 25 October 2001 (25.10.2001) US 7 August 2002 (07.08.2002) US

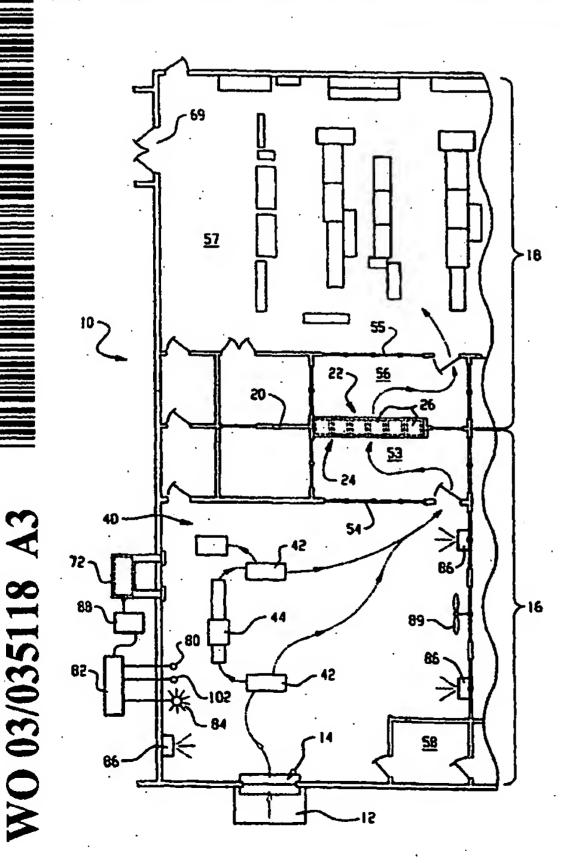
- (71) Applicant: STERIS INC. [US/US]; 43425 Business Park Drive, Temecula, CA 92590 (US).
- (72) Inventors: MIELNIK, Thaddeus, J.; 7546 Hunting Lake Drive, Concord, OH 44077 (US). KARLE, David, A.; 9201 Mohawk Road, Girard, PA 16417 (US). BIGGIE, Alex, D.; 5731 Silvertree Court, Madison, OH 44057 (US). BIEBESHEIMER, William, John, Thomas; 4785

South Ridge Road, Perry, Oll 44081 (US). BURKE, Peter, A.; 7 Mayacoo Court, Skillman, NJ 08558 (US). MCDONNELL, Gerald, E.; 7 Millenium Court, Lower Brook Street, Basingstoke (GB). RHODES, Chad; 206 Briar Ridge Lane, Lake Villa, IL 60046 (US). KOPIS, Elaine, M.; 4545 Little Rock Road, St. Louis, MO 63128 (US).

- (74) Agents: KOCOVSKY, Thomas, E., Jr. et al.; Fay, Sharpe, Fagan, Minnich & McKee, LLP, 1100 Superior Avenue, 7th floor, Cleveland, Oll 44114 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, HD, HL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW.

[Continued on next page]

(54) Title: DECONTAMINATION OF CRITICAL MAIL



(57) Abstract: A system for handling mail is in the form of a modular facility (10), which is capable of being isolated from the surrounding environment. The modular facility includes an enclosure or sorting area (40) for receiving and sorting incoming mail. A decontamination system (22) receives sorted mail and decontaminates the mail with a oxidizing gas, such as ethylene oxide. A clean room (32), isolated from the enclosure and spaced from the enclosure by the decontamination system, is used for receiving processed mail from the decontamination system and sorting the mail for distribution. A source (92) of a decontaminant gas, such as vapor hydrogen peroxide, is fluidly connected with the enclosure for supplying the decontaminant gas to the enclosure in the event that the sorting room is contaminated or suspected of being contaminated with a pathogenic biological or chemical agent.



(84) Designated States (regional): ARIPO patent (GII, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(88) Date of publication of the international search report: 23 October 2003

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

with international search report

INTERNATIONAL SEARCH REPORT

Internal I Application No PCT/US 02/34307

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61L2/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS

| C. DOCUM | NTS CONSIDERED TO BE RELEVANT | |
|------------|---|-----------------------|
| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| Х,Р | US 2002/124664 A1 (CALL CHARLES J ET AL) 12 September 2002 (2002-09-12) paragraphs '0035!,'0108!-'0129!,'0212!,'0327! | 1-5,7, 31,33,34 |
| A | WO 99 32162 A (CARMEN GARY B ;WIRTZ STEPHEN K (US)) 1 July 1999 (1999-07-01) page 3, paragraph 3 -page 14, paragraph 1; figures 1,2 | 1-34 |
| A,P | US 2002/150500 A1 (CARMAN GARY B ET AL) 17 October 2002 (2002-10-17) paragraphs '0045!, '0051!-'0055!; figures 1,3 | 1-34 |
| | -/ | |

| Patent family members are listed in annex. |
|---|
| "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family |
| Date of mailing of the international search report |
| 19/05/2003 |
| Authorized officer |
| |

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Internal Application No
PCT/US 02/34307

| C.(Continu | ation) DOCUMENTS CONSIDERED TO BE RELEVANT | PCT/US 02 | |
|------------|--|-----------|-----------------------|
| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | | Relevant to claim No. |
| 4 | US 2 075 845 A (GROSS PAUL M ET AL) 6 April 1937 (1937-04-06) page 3, right-hand column, line 47 -page 4, left-hand column, line 46 | | |
| A,P | RICE, RIP G.: "Ozone and Anthrax - Knowns and Unknowns" OZONE SCIENCE & ENGINEERING, vol. 24, pages 151-158, XP001147252 page 157, left-hand column, paragraph 2 -right-hand column, paragraph 1 | | 1-34 |
| | | | • |
| | | | |
| | | | |
| | | | |
| | | | |
| | · | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | . , |
| | | | |
| l li | | | |
| | | | |
| | | | |
| İ | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | 8 | |
| | | | |

INTERNATIONAL SEARCH REPORT

muormanon on patent taminy members

Internal al Application No PCT/US 02/34307

| Patent document cited in search report | | Publication date | | Patent family member(s) | Publication date |
|--|----------------------------|---|------|-------------------------|------------------|
| US 2002124664 | A1 | 12-09-2002 | US | 2001029793 A1 | 18-10-2001 |
| , | | | US | 6363800 B1 | 02-04-2002 |
| | • | | US | 2002157993 A1 | 31-10-2002 |
| | | | CA | 2348333 A1 | 01-08-2002 |
| | | | GB | 2371768 A | 07-08-2002 |
| | P 1821 1827 1933 1933 2011 | | US | 2002179499 A1 | 05-12-2002 |
| WO 9932162 | Α | 01-07-1999 | AU | 1997799 A | 12-07-1999 |
| | | • | EP | 1042011 A1 | 11-10-2000 |
| | | | JP | 2001526093 T | 18-12-2001 |
| | • | | US | 2002150500 A1 | 17-10-2002 |
| | | | WO | 9932162 A1 | 01-07-1999 |
| • | | | US | 2002182104 A1 | 05-12-2002 |
| | · | • | US | 6284193 B1 | 04-09-2001 |
| | | • | US | 6337048 B1 | 08-01-2002 |
| | يروبين سية بكتب شدة خ | . برور برور سرو سرو درو درو درو برور برور درو درور درور د | US | 6334979 B1 | 01-01-2002 |
| US 2002150500 | A1 | 17-10-2002 | US | 6284193 B1 | 04-09-2001 |
| • | | | US | 2002182104 A1 | 05-12-2002 |
| | | • | US | 6337048 B1 | 08-01-2002 |
| | | | US | 6334979 B1 | 01-01-2002 |
| | | | AU | 1997799 A | 12-07-1999 |
| • | | | EP | 1042011 A1 | 11-10-2000 |
| • | | | JP | 2001526093 T | 18-12-2001 |
| | | | ΜO | 9932162 A1 | 01-07-1999 |
| US 2075845 | Α | 06-04-1937 | NONE | | |

Form PCT/ISA/210 (patent family ennex) (July 1992)

THIS PAGE BLANK (USPTO)